UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,145	12/20/2007	Peter Prehm	DFM0004/US (40570-8002)	9831
33072 7590 04/05/2011 KAGAN BINDER, PLLC SUITE 200, MAPLE ISLAND BUILDING			EXAMINER	
			POLANSKY, GREGG	
221 MAIN STREET NORTH STILLWATER, MN 55082			ART UNIT	PAPER NUMBER
			1629	
			MAIL DATE	DELIVERY MODE
			04/05/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
Office Action Occurrence	10/566,145	PREHM, PETER		
Office Action Summary	Examiner	Art Unit		
	GREGG POLANSKY	1614		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	ely filed the mailing date of this communication. (35 U.S.C. § 133).		
Status				
<ul> <li>1) ☐ Responsive to communication(s) filed on <u>27 Ja</u></li> <li>2a) ☐ This action is <b>FINAL</b>. 2b) ☐ This</li> <li>3) ☐ Since this application is in condition for allowant closed in accordance with the practice under E</li> </ul>	action is non-final.  nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) 1-69 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-69 are subject to restriction and/or expressions.				
Application Papers				
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the construction of the constructi	epted or b) $\square$ objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)	a> □ 1	(PTO 412)		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)         Paper No(s)/Mail Date     </li> </ol>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite		

## **DETAILED ACTION**

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-12 and 37-46, drawn to methods of treating a disease associated with excess transport of hyaluronan across a lipid bilayer.

Group II, claims 13-36, 47-69, drawn to methods for screening for a compound.

## 2. REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

## WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
  - (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Application/Control Number: 10/566,145 Page 4

Art Unit: 1614

3. The groups of inventions listed above do not relate to a single general inventive

concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: Groups I and II are

drawn to two distinct methods and therefore are not drawn to the above combinations of

categories considered to have unity of invention.

4. This application contains claims directed to more than one species of the generic

invention. These species are deemed to lack unity of invention because they are not so

linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Group I is elected Applicant must elect:

a. A specific ABC-transporter subfamily (e.g., ABC-C (MRP)-subfamily);

b. A specific inhibitor of the elected ABC-transporter subfamily (e.g.,

verapamil); and

c. A specific disease subject to treatment (Note: This must be a specific

disease; for example, osteoarthritis).

If Group II is elected Applicant must elect:

a. A specific ABC-transporter subfamily (e.g., ABC-C (MRP)-subfamily); and

b. A specific inhibitor of the elected ABC-transporter subfamily (the "test"

compound; e.g., verapamil);

Applicant is required, in reply to this action, to elect species (as explained above)

to which the claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: All claims are generic.

Election of species not specifically disclosed as filed may be considered new matter.

2. Applicant is advised that the reply to this requirement to be complete must include (i) an election of species and an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Application/Control Number: 10/566,145 Page 6

Art Unit: 1614

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof.

Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case.

Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on (571) 272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/566,145 Page 7

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/ Examiner, Art Unit 1614

/James D Anderson/ Primary Examiner, Art Unit 1629